RE*MARK*S

In the Office Action, claims 1-36 are rejected under 35 U.S.C. § 112, first paragraph; claims 1-4, 9-12, 15-19, 22, 23, 26-30, 33 and 34 are rejected under 35 U.S.C. § 102; and claims 1-36 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper as set forth in detail below.

At the outset, the Patent Office rejects claims 1-36 under 35 U.S.C. § 112, first paragraph. The Patent Office alleges that the specification is not enabling with respect to a ratio of omega 3 to omega 6 of 5:1 to 10:1 as claimed.

Applicants believe that the specification provides sufficient support for the claim terms at issue as discussed above. For example, the specification provides a method for improving muscle synthesis that includes administering to an individual a therapeutically effective amount of a composition wherein the composition includes, in part, a lipid source having an omega 3:6 fatty acid ratio of about 5:1 to about 10:1. See, Specification, p. 2, line 31 to p. 3, line 1. Further, the claims as originally filed also provide support for this limitation. In view of same, Applicants believe that one skilled in the art would be able to practice the claimed invention contrary to the Patent Office's position.

Based on at least these reasons, Applicants believe that the claimed invention satisfies the requirements pursuant to 35 U.S.C. § 112, first paragraph. Therefore, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-4, 9-12, 15-19, 22, 23, 26-30, 33 and 34 are rejected under 35 U.S.C. § 102 in view of U.S. Patent No. 6,200,950 ("*Mark*"). The Patent Office essentially asserts that the *Mark* reference discloses each and every feature of the claims at issue.

Applicants believe that this rejection is improper. Of the pending claims at issue, claims 1, 15 and 26 are the sole independent claims. Claim 1 recites a method for improving muscle synthesis; claim 15 recites a method for preventing muscle loss in an individual at risk of same; and claim 26 recites a method for accelerating muscle mass recovery. As defined in each of claims 1, 15 and 26, the method includes administering a therapeutically effective amount of a composition wherein the composition includes a protein source, whey protein, a lipid source, a carbohydrate source and a macronutrient profile that at least includes vitamin E and vitamin C as claimed.

Applicants have found that the methods and nutritional supplements of the claimed invention are particularly suitable for providing supplemental nutrition to an individual requiring, or that could benefit from, increased protein muscle synthesis. Such an individual may include the elderly, anorexic patients or those who have an impaired ability to digest other sources of protein. Due to its components, the supplement is more rapidly digested and therefore the patient is more likely to consume a therapeutically effective amount of the supplement or other food to provide for adequate nutrition. See, Specification, page 7, lines 11-16.

In contrast, Applicants believe that the cited art is deficient with respect to the claimed invention. At the outset, the primary focus of *Mark* relates to a composition that is designed to address the general nutritional needs of a specific class of persons, namely, metabolically stressed patients as disclosed in *Mark*, for example, at column 6, lines 13-29. Indeed, one skilled in the art viewing same would clearly understand that the compositions as disclosed in *Mark* are for seriously ill patients, such as due to early transitioning from TPN, catabolic conditions and the like.

In contrast, the claimed methods are directed to improve muscle protein synthesis (claim 1), prevent muscle loss (claim 15) and accelerate muscle mass recovery (claim 26). Indeed, *Mark* does not even mention the word "muscle", let alone compositions that could be used for improving muscle protein synthesis, preventing muscle loss or accelerating muscle recovery as claimed, at all within the entire text. *Mark* merely suggests that the compositions are purportedly utilized to treat metabolically stressed patients which are defined as "patients who, due to either disorder or condition, are unable to tolerate whole protein diets and need fluid restriction, while at the same time, cannot tolerate elevated protein levels or excess fluid." See, *Mark*, column 6, lines 13-20.

Further, the class of persons at need of such help as improving muscle protein synthesis, preventing muscle loss or accelerating muscle recovery as claimed is a very different class from the seriously ill subjects as disclosed in *Mark*. As previously discussed, the claimed invention can be utilized with respect to the elderly, the convalescent, anorexic patients and the like.

Based on at least these differences, Applicants believe that *Mark* is clearly distinguishable from the claimed invention. Therefore, Applicants respectfully submit that *Mark* fails to anticipate or arguably render obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, claims 1-36 are rejected under 35 U.S.C. § 103. More specifically, claims 1-4, 6-12, 15-23 and 26-34 are rejected in view of *Mark* and further in view of *Whitney*; claim 5 is rejected in view of *Mark* and *Whitney* and further in view of *Ballevre et al.* or *Kawasaki et al.* or *Etzel*; and claims 13, 14, 24, 25, 35 and 36 are rejected in view of *Mark* and *Whitney* and further in view of Cavaliere et al. Applicants believe that the obviousness rejections are improper.

Of the pending claims at issue, claims 1, 15 and 26 are the sole independent claims as discussed above. Applicants believe that the *Mark* reference is deficient with respect to the subject matter as defined therein based on at least substantially the same reasons as discussed above. Therefore, *Mark* on its own is deficient with respect to the claimed invention.

Further, Applicants believe that the remaining cited references alone or even if combinable fail to remedy the deficiencies of *Mark*. With respect to *Whitney*, the Patent Office merely relies on same as purportedly suggesting that protein is necessary for muscle building along with carbohydrates and minerals. See, Office Action, page 4. Indeed, the portions of *Whitney* relied upon by the Patent Office suggest that diet alone cannot be utilized to build body protein, but "the way to make muscle cells grow is to put a demand on them, that is, to make them work." See, *Whitney*, page 178, column 3. Further, *Whitney* merely and only generally suggests that protein is available by eating an adequate diet without excess protein but with ample calories. See, *Whitney*, page 178, column 3 to page 179, column 1. Indeed, the clear focus of *Whitney* relates to building muscles in athletes based on a diet and exercise regime. Therefore, even if combined with *Mark*, *Whitney* is deficient with respect to the claimed invention.

Moreover, the remaining references cannot be relied upon to remedy the deficiencies of *Whitney* and *Mark*. With respect to *Ballevre*, *Kawasaki* and *Etsel*, the Patent Office merely relies on same for their alleged teachings regarding nutritional compositions that include GMP. With respect to the Cavaliere reference, the Patent Office merely relies on same for its alleged teaching regarding a composition that contains bifido bacterium and fiber, such as inulin and oligosaccharides. What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejections. Of course, this is not proper.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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